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Serial No.: 10/027,226 Confirmation No.: 9039 Filed; December 20, 2001

Amendment and Response

For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES FROM BIOLOGICAL MIXTURES USING A HYDROPHILIC SOLID SUPPORT IN A HYDROPHOBIC MATRIX

Remarks

The Office Action mailed January 7, 2004 has been received and reviewed. Claims 2 and 29 having been canceled, claims 1, 3, 5, 26, 28, 30, 32, 50, 55, 62-64, and 72 having been amended, and claim 78 having been added, the pending claims are claims 1, 3-28, 30-55, and 62-78. Claims 1-49 having been withdrawn from consideration by the Examiner, claims 50-55 and 62-78 are currently under examination.

The specification has been amended to update publication information for recited pending applications.

Claims 1, 5, 26, 28, 32, 50, 55, and 62-64 have been amended to recite particles of hydrophilic solid support, which is supported, for example by originally filed claims 2 and 29 (now canceled). Claims 3 and 30 have been amended to depend from claims 1 and 28, respectively. Claim 72 has been amended to correct a typographical error so that claim 72 properly depends from claim 70.

New claim 78 is supported, for example, by originally filed claims 20 and 50. Reconsideration and withdrawal of the rejections are respectfully requested.

Objection to the Claims

The Examiner objected to claims 68-77 under 37 C.F.R. §1.75 (c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Examiner alleged that dependent claims 68-77 recite language directed to material tested in the devices, which would also be an intended use that would be given no patentable weight during examination. Applicants respectfully traverse the objection.

37 C.F.R. §1.75(c) states that "[o]ne or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application."

Applicants respectfully submit that claims 68-77 refer back to and further limit claim 39 as required by 37 C.F.R. §1.75(c).

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Specifically, claim 39 recites not only a volume for containing a biological sample mixture, but also that the device is operable to remove small negatively charged organic molecules from the biological sample mixture. Claims 68-76 recite further language directed to the biological sample mixture and/or the small negatively charged organic molecules. Claim 77 recites further language directed to the device. Thus, claims 68-77 refer back to and further limit language recited in claim 39 as required by 37 C.F.R. §1.75(c). Therefore, Applicants respectfully submit that claims 68-77 are in proper dependent form.

The Examiner further asserted that some of the language would be an intended use that would be given no patentable weight during examination. Applicants disagree that the language at issue is related to "an intended use." Moreover, Applicants respectfully submit that whether or not language in a claim is given patentable weight by the Examiner during examination is immaterial to the determination of proper claim form pursuant to 37 C.F.R. §1.75(c).

Based on the remarks presented herein above, Applicants respectfully submit that claims 68-77 are in proper dependent form. Reconsideration and withdrawal of the objection to the claims is respectfully requested.

Provisional Obviousness-Type Double Patenting Rejections

Claims 50-53 and 68-77 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-58 of copending U.S. Application No. 10/417,609 in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.). Further, claims 50-53 and 68-77 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-42 of copending U.S. Application No. 10/027,222 in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.). As previously noted, upon an indication of otherwise allowable subject matter and in the event these rejections are maintained, Applicants will provide an appropriate response.

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In the event that the provisional obviousness-type double patenting rejections are the only rejections remaining in the present application, the Examiner is respectfully requested to withdraw the provisional obviousness-type double patenting rejection and allow the present application to issue as a patent pursuant to M.P.E.P. §822.01.

Rejection under 35 U.S.C. §103

The Examiner rejected claims 50-52, 64-65, and 68-77 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.). Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §706.02(j). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

Independent claim 50 (as amended) recites a device that includes a solid-phase extraction material including particles of a hydrophilic solid support at least partially embedded within a hydrophobic matrix. Nelson et al. and Dusterhoft et al. were both discussed in the Amendment and Response submitted by Applicants on October 3, 2003, and the discussion is incorporated herein by reference. Specifically, Dusterhoft et al. discloses that "the resin preferably comprises both hydrophilic and hydrophobic segments within its molecules" (column 10, lines 30-31). However, Applicants respectfully submit that neither Nelson et al. nor Dusterhoft et al. teach or suggest particles of a hydrophilic solid support at least partially embedded within a hydrophobic matrix (e.g., claim 50, as amended). Thus, Applicants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness.

Applicants also request correction or clarification of remarks made by the Examiner in the Office Action mailed January 7, 2004. The Examiner alleged that Applicants argued that Nelson et al. does not teach a plurality of arrays (page 6, paragraph 11). Applicants respectfully

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disagree with the Examiner's characterization of Applicants' arguments. Applicants did argue that Dusterhoft et al. failed to disclose or suggest a device including a plurality of process arrays (e.g., page 20, lines 1-2 of Amendment and Response submitted October 3, 2003); and that Neslon et al. in view of Dusterhoft et al. failed to disclose or suggest a device as disclosed in claim 50 further including a plurality of independent process arrays (e.g., page 21, lines 19-21). However, Applicants did not argue that Nelson et al. does not teach a plurality of arrays as stated by the Examiner. An appropriate correction or clarification of the Examiner's remarks is respectfully requested in the next Official Communication.

For at least the reasons presented herein above, Applicants respectfully submit that claims 50-52, 64-65, and 68-77 are patentable over Nelson et al. in view of Dusterhoft et al.

The Examiner also rejected claim 53 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.) as applied above, and further in view of U.S. Pat. No. 6,319,469 (Mian et al.).

Claim 53 depends from claim 50 (as amended). Applicants respectfully submit that Mian et al. fail to cure the deficiencies of Nelson et al. in view of Dusterhoft et al. as discussed herein above.

Further, the Examiner rejected claims 62-63 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.) as applied above, and further in view of U.S. Pat. No. 6,632,399 (Kellogg et al.).

Claims 62-63 depend from claim 50 (as amended). Applicants respectfully submit that Kellogg et al. fail to cure the deficiencies of Nelson et al. in view of Dusterhoft et al. as discussed herein above.

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Finally, the Examiner rejected claims 54-55 and 66-67 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Neslon et al.) in view of U.S. Pat. No. 6,451,260 (Dusterhoft et al.) as applied above, and further in view of U.S. Pat. No. 4,399,009 (Chisholm).

Claims 54-55 and 66-67 depend from claim 50 (as amended). Applicants respectfully submit that Chisholm fails to cure the deficiencies of Nelson et al. in view of Dusterhoft et al. as discussed herein above. Furthermore, Chisholm is directed to an "electrolytic cell and method" (title). Applicants respectfully submit that the combination of documents cited by the Examiner could only occur by the impermissible use of hindsight reasoning.

In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

New Claim

New claim 78 includes the language of, for example, claim 50. Applicants respectfully submit that claim 78 is patentable for at least the reasons for the patentability of claim 50 discussed herein above, in addition to reasons related to the additional subject matter recited therein. Applicants respectfully request that the Examiner enter, consider, and pass new claim 78 on to allowance.

Request for Rejoinder

Claims 1-49 (as amended) recite methods of using a device as recited, for example, in claim 50 (as amended). Specifically, independent claims 1, 20, 26, 28, and 47 (as amended) recite language from independent claim 50 (as amended). Upon an indication of claim 50 being allowable, Applicants respectfully request that the method claims (e.g., claims 1-49) also be examined and passed on to allowance pursuant to M.P.E.P. §821.04. See, for example, In re

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Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fec. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for PARTHASARATHY et al.

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this ______ day of May, 2004, at ______ (Central Time).

By: Rachel Gaglind. Gulan Name: Rachel Gaglind. - Grahan